

pharmaceutical composition without chelating agent”; 3) “solid”; and 4) “gel”.¹ A Markman hearing was held on July 21, 2010. The Court has considered the written submissions of the parties, along with the certifications and testimony of Plaintiffs’ expert, Dr. Stephen R. Byrn, Ph.D., and Defendant’s expert, Dr. Harry G. Brittan, Ph.D. The Court shall construe the terms in the context of the asserted claims as set forth herein.

I. Overview of the ’882 Patent

The ’882 patent, entitled “Drug-Resin Complexes Stabilized by Chelating Agents,” claims certain pharmaceutical compositions using a drug-resin complex and a chelating agent and certain methods of making these pharmaceutical compositions. The claims of the ’882 patent include Delsym and its method of production.

The active ingredient in Delsym is dextromethorphan, a common cough suppressant that has been on the market for at least 50 years. Dextromethorphan is sometimes referred to as DM, as in the cough syrup Robitussin DM®. Delsym contains dextromethorphan in an extended release form so it can be taken less frequently than a conventional cough syrup. The dextromethorphan in Delsym is complexed to fine particles of resin to form what is called a drug-resin complex. This drug-resin complex, in turn, is dispersed in water with inactive ingredients like high fructose corn syrup and flavorings to make a pharmaceutical product. When swallowed, the dextromethorphan is released from the drug-resin complex over a period of time. The use of dextromethorphan in a drug-resin complex is old technology, as Delsym has been on the market since the

¹ Although Plaintiffs set forth their respective proposed constructions of these latter two disputed claim terms, they nevertheless argue that the disputed terms need not be construed as they are widely used and readily understood by those of ordinary skill in the art.

early 1980's. The patent that originally covered it, U.S. Patent 4,221,778, was applied for by UCB's predecessor and issued in 1980, and expired in 1997.

Tris Pharma contends that it is no coincidence that the '882 patent at issue was applied for in 1997, the same year that the earlier patent covering its formulation was expiring. According to Tris Pharma, this evergreening patent could not, of course, validly cover any of the subject matter in the prior art. Accordingly, the '882 patent claims an "improved" formulation of Delsym to which an extra ingredient has been added. That ingredient is not another drug, but is the common preservative or stabilizer called edetate disodium (more generally claimed in the '882 patent as "EDTA or a salt of EDTA").²

Tris Pharma contends that the problem with Plaintiffs' infringement action is that Tris Pharma's proposed product does not contain EDTA. While Tris Pharma uses EDTA to remove metal ions from the resin, it contends that the EDTA is washed out before the resin is used as an ingredient in the manufacture of its pharmaceutical product. Tris Pharma argues that Plaintiffs are in effect asking this Court to rewrite, in the guise of claim construction, their patent claims – which are directed to a pharmaceutical formulation like Delsym to which EDTA has been added – to embrace the use of EDTA in a manufacturing process even when the EDTA is neither added to nor present in the pharmaceutical that will be sold to consumers.

Plaintiffs contend that in the '882 patent, the chelating agent acts as a scavenger for metal ions by forming unusually stable bonds with those ions, thus rendering them unavailable to catalyze the oxidative process (which causes drug degradation). Plaintiffs

² Tris Pharma contends that EDTA is probably the best-known pharmaceutical stabilizer and that in addition to pharmaceuticals, it is also commonly added to foods and beverages, cosmetics, shampoos and other products where spoilage or stability is a potential concern.

emphasize that because the chelating agent need only render the trace metal ions in the resin unavailable to act as catalysts, the timing of its addition during the manufacturing process is not of great significance and can be added “at any time during the process. Plaintiffs’ Opening Br. at 4 (quoting ’882 patent, col. 3, ll. 64-67; col. 4, ll. 10-14).

II. General Legal Claim Construction Standards

Claims define the scope of the inventor's right to exclude. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope, and is a determination exclusively for the court as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 978-79 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370 (1996). Indeed, the court can only interpret claims, and “can neither broaden nor narrow claims to give the patentee something different than what it has set forth” in the specification. E. I. Du Pont de Nemours v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art (“POSA”). Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1372 (Fed. Cir. 2001); see also Markman, 52 F.3d at 986 (“The focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the terms to mean”); Phillips, 415 F.3d at 1312-13. In construing the claims, the court may examine both intrinsic evidence (e.g., the patent, its claims, the specification and prosecution history) and extrinsic evidence (e.g., expert reports, testimony and anything else). Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999). However, claims may not be construed with reference to the

accused device, which means that the court may not construe a claim to fit the dimensions of the accused device, thus to prejudice the claim construction by “excluding or including specific features of the accused device.” Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1330 (Fed. Cir. 2006). Nevertheless, the knowledge of the accused device before or during claim construction is not only permissible, but also necessary to claim construction because it “supplies the parameters and scope of the infringement analysis.” Id. at 1330-31; Lava Trading Inc. v. Sonic Trading Mgmt., 445 F.3d 1348, 1350 (Fed. Cir. 2006).

In interpreting the disputed terms, it is well settled that the Court should look first to the intrinsic evidence. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1356, 1362 (Fed. Cir. 1996). Generally, words in patent claims are given their ordinary meaning as understood by one of ordinary skill in the art at the priority date of the patent application. Dow Chem., 257 F.3d at 1372; K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1362 (Fed. Cir. 1999). The claims must be construed objectively in the context of both the particular claim and the entire patent because “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” and claim terms are normally used consistently throughout the patent. Phillips, 415 F.3d at 1313-14.

Moreover, courts are instructed to look to the specification, which is a written description of the invention. “[C]laims ‘must be read in view of the specification, of which they are a part.’” Phillips, 415 F.3d at 1315 (quoting Markman, 52 F.3d at 979). Indeed, the specification is perhaps “the single best guide to the meaning of a claim term” due to its statutory requirements of being in “full, clear, concise, and exact terms.” Phillips, 415 F.3d at 1316; see 35 U.S.C. § 112. “The specification acts as a dictionary

when it expressly” or implicitly defines terms used in the claims. Markman, 52 F.3d at 979. Thus, it effectively limits the scope of the claim. On Demand Mach. Corp. v. Ingram Industries, Inc., 442 F.3d.1331, 1340 (Fed. Cir. 2006). Due to its nature, “the specification ‘is always highly relevant to the claim construction analysis. Usually it is dispositive.’” Id. (quoting Vitronics Corp., 90 F.3d at 1582).

Extrinsic evidence includes all evidence external to the patent and prosecution history, i.e., expert and inventor testimonies, dictionaries, and learned treatises. Markman, 52 F.3d at 980. It is considered only where the intrinsic evidence does not provide a sufficient description to resolve ambiguities in the scope of the claim. See Vitronics, 90 F.3d at 1583; Johnson Worldwide Assoc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). However, the Federal Circuit cautioned, in Phillips, that dictionary definitions should not be used to interpret patent claim terms in a manner that is divorced from the context and description of the invention in the specification. Phillips, 415 F.3d at 1321. The Phillips Court reasoned that because of the nature of the patent claims, the dictionary definitions, as extrinsic evidence, are usually less reliable than the patent documents themselves in establishing the ordinary meaning of a claim term. Phillips, 415 F.3d at 1314; Toro Co. v. White Consol. Indus., 199 F.3d 1295, 1299 (Fed. Cir. 1999). Ultimately, extrinsic evidence cannot be used to vary or contradict claim terms when their meanings are discernible from intrinsic evidence. C. R. Bird, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004).

III. Discussion

A. A Pharmaceutical Composition

Plaintiffs' Proposed Construction	Tris Pharma's Proposed Construction
A compound or mixture formed in or as a result of the preparation of a drug product	A drug product suitable for administration to a patient

The principal claim construction dispute centers on the question of whether the claimed “pharmaceutical composition” includes products formed in or as a result of the preparation of a drug product, or, as Tris Pharma argues, is limited to a final dosage form that may be administered to a patient.

Tris Pharma contends that any construction that does not require presence of the claimed amount of EDTA in combination with the drug-resin complex – such as Plaintiffs’ construction that embraces the mere use of EDTA as a processing aid for raw materials that is rinsed away and not found in the pharmaceutical composition – is inconsistent with the intrinsic evidence. Tris Pharma posits that the entire point of the ’882 patent is adding EDTA to certain pharmaceutical compositions in order to enhance their stability. According to Tris Pharma, the quantity of EDTA required is generally claimed by the observed result. Specifically, Tri Pharma states that the independent claims require comparing a pharmaceutical composition with EDTA to an “otherwise identical pharmaceutical composition” without EDTA. Defendant’s Opening Brief, at *5. The claimed quantity of EDTA is that which reduces degradation of the drug by more than 20% after twelve months of storage. *Id.* Tris Pharma contends that this required comparison is seen in claim 23, which states the following:

23. A method for improving the stability of a pharmaceutical composition that contains a drug-resin complex comprising

adding a chelating agent [EDTA] in an amount effective to reduce the rate of degradation of the drug in the drug-resin complex by more than 20 percent over twelve months of storage at room temperature relative to an otherwise identical pharmaceutical composition without the chelating agent;

wherein the chelating agent is selected from EDTA or a salt of EDTA; and

wherein the drug in the drug-resin complex is selected from dextromethorphan, codeine, morphine, hydrocodone, pseudoephedrine, or phenylpropanolamine.

Tris Pharma asserts that claim 23 requires comparing the degradation of (i) a drug in the drug-resin complex of “a pharmaceutical composition” that contains EDTA to that of (ii) a drug in an “otherwise identical” pharmaceutical composition without EDTA. As Tris Pharma explains, this comparison reflects the purported invention of improving the shelf-life of Delsym. Id. at *6. Tris Pharma argues that for the “claimed comparison to be apples-to-apples”, the two things to be compared must both be pharmaceutical compositions containing drug-resin complexes. Id.

According to Tris Pharma, the pharmaceutical composition is not simply the drug resin complex, but rather the composition that contains the drug-resin complex and (in one form of the composition) the EDTA. Tris Pharma contends that the specification teaches that the pharmaceutical composition is a finished drug product, rather than simply a component (e.g., a drug-resin complex) of a finished drug product by stating that “drug-resin complexes” are suitable for use in “pharmaceutical compositions.” Tris Pharma Opening Br. at 6 (quoting the ’882 patent, col. 13, ll. 30-31). Tris Pharma contends that the specification of the ’882 patent shows that pharmaceutical composition is the finished

product, as it is used consistently to indicate the finished drug product, not individual ingredients or an intermediate step in a manufacturing process. For example, Tris Pharma cites the fact that the specification discloses suitable dosage forms, such as tablets, and routes of administration, such as oral, for “pharmaceutical compositions” that can only be referring to finished products. See Tris Pharma Opening Br. at 6-7 (quoting the ’882 patent, col. 5, ll. 31-36; col. 13, ll. 30-36). Tris Pharma notes that claims 14 and 15 similarly recite dosage forms and modes of administration for the pharmaceutical composition, again necessarily referencing only finished products. Tris Pharma argues that the use of “pharmaceutical composition in claims 14 and 15 is pertinent to the construction of “pharmaceutical composition” in claim 23 because claims are generally construed in a consistent manner throughout the claims. Id. at 7 (citing Research Plastics, Inc. v. Fed Packaging Corp., 421 F.3d 1290, 1295 (Fed. Cir. 2005) (“claim terms are presumed to be used consistently throughout the patent, such that the usage of a term in one claim can often illuminate the meaning of the same terms in other claims”).

Tris Pharma also notes that the specification of the ’882 patent incorporates by reference U.S. Patent 4,221,778 (the “’778 patent”) which is also directed to drug-resin complexes stabilized by chelating agents. Tris Pharma points out that the ’778 patent uses the terms “pharmaceutical preparation” and “pharmaceutical composition” interchangeably. The ’778 patent provides as follows:

The present invention is concerned with pharmaceutical preparations comprised of ion exchange resins having a pharmacologically active drug absorbed thereon to form a drug resin complex wherein at least a substantial portion of the complex particles have been treated with a solvating agent and provided with a water-permeable diffusion barrier coating whereby a prolonged continuous release of the drug is obtainable under conditions encountered in the gastrointestinal tract.

Tris Pharma reasons that the '778 patent must therefore be a drug product suitable for administration to a patient since it is released in the gastrointestinal tract. Tris Pharma points out that the '778 patent also discloses that the pharmaceutical preparations and compositions can be administered using certain routes of administration and using certain dosage forms:

In addition to oral administration, the preparations of the subject invention are also suitable for topical, rectal, vaginal or nasal administration in dosages varying over a wide range, for example from about 0.1 to about 1000 mg, depending on the nature of the drug and its intended usage. The compositions can take the form of tablets, powders, capsules, liquid suspensions or other conventional dosage forms.

'778 patent, col. 3, ll. 30-38. Tris Pharma reasons that, to be administered using the specified dosage forms, the pharmaceutical compositions must be drug products suitable for administration to a patient.

Tris Pharma points out that the specification of the '882 patent further emphasized that the pharmaceutical composition contains the drug-resin complex and EDTA (chelating agent) when distinguishing the claimed invention from the prior art. Tris Pharma notes, for example, that the background of the invention states that "none of the patents described above disclose a pharmaceutical composition in the form of a solid or gel that comprises a drug-resin complex and a chelating agent." Tris Pharma Opening Br. at 8-9 (quoting the '882 patent, col. 3, ll. 21-23).

Tris Pharma further cites the prosecution history of the '882 patent as confirming that a pharmaceutical composition is a finished drug product. For example, Tris Pharma cites the following statement, which it claims, evidences the fact that the applicant

distinguished its invention from prior art that did not combine the chelating agent and drug-resin complex in the pharmaceutical composition:

JP 46-40351 does not disclose the use of a drug in combination with an ion exchange resin. The example in the abstract of JP 46-40351 describes a preparation containing water, an ion-exchange resin, tartaric acid, carboxymethylcellulose, sweeteners, and perfume. Tartaric acid is a chelating agent; carboxymethyl-cellulose is a thickener and emulsion stabilizer; and sodium saccharin and sodium cyclamate are sweeteners. No drug is described. The claimed invention cannot be obvious over a reference that does not contain a drug.

July 7, 1998 Amendment and Response in U.S. Patent App. 08/834,359, TRIS015289.

Tris Pharma argues that when construed in view of the invention disclosed in the specification and prosecution history, it is clear that the construction of pharmaceutical composition must be limited to finished products.

Tris Pharma states that its construction of pharmaceutical composition, as a finished drug product, is consistent with the ordinary meaning of the term, citing to both general purpose and scientific dictionaries, which define pharmaceutical as a “medicinal drug.” Tris Pharma contends that claims 5, 6, 14 and 15 (which are not asserted) further confirm that a pharmaceutical composition is a finished drug product.³

Plaintiffs counter that their construction of a pharmaceutical composition as a compound or mixture formed in or as a result of the preparation of a drug product is compelled by the ordinary and customary meaning of the terms and the intrinsic evidence.

³ Tris Pharma contends that while Plaintiffs knew that the unasserted claims were at issue from Tris Pharma’s Preliminary Proposed Claim Construction and the Joint Claim Construction and Prehearing Statement, they failed to offer their own proposed constructions. Accordingly, Tris Pharma contends that its construction of those terms should be adopted by default. See Tris Pharma Responsive Brief at 10 (citing Info. Tech. Innovation, LLC v. Motorola, Inc., 391 F.Supp. 2d 719, 724 (N.D. Ill. 2005) (by failing to present alternative construction, party “waived their right to present alternative constructions of the terms.”)).

Citing Webster's Dictionary, Plaintiffs point out that the term "pharmaceutical" means "of, relating to, or engaged in pharmacy," and "pharmacy," in turn, refers to "the practice of preparing, preserving, compounding, and dispensing drugs." Plaintiff's Opening Brief, at *11. Likewise, Plaintiffs argue, "composition" is commonly understood to mean "a product of mixing or combining various elements or ingredients." Id.

Looking to the '882 patent itself, Plaintiffs contend that the term pharmaceutical composition, while not defined, is used throughout the specification (either in its full form or in the abbreviated form "composition") to describe various compounds or mixtures formed during, or as the result of, the preparation of a drug product. Accordingly, Plaintiffs argue that the term encompasses both intermediary products and final products. In support of this construction, Plaintiffs cite the fact that in the '882 patent, the intermediary combination of the drug and resin is referred to as a "composition":

The reaction or complexation of a drug with an ion exchange resin forms a composition known as a drug-resin complex.

Plaintiffs. Opening Br. at 12 (quoting '882 patent, co. 1, ll. 14-16). Plaintiffs further cite the fact that the intermediary product resulting from dispersing the resin alone in water, before complexation with the drug, is also referred to as a "composition":

Ion exchange resins are usually made from a polymer backbone with various displaceable functional groups ionically bonded to the polymer. In water the functional groups of the resin ionize. The polymer chains are also typically cross linked, leading to a gel-like insoluble composition formed in beads.

Plaintiffs Opening Br. at 12 (quoting '882 patent, col. 1, ll. 60-65).

Turning to the examples of the invention set forth in the '882 patent, Plaintiffs argue that they clearly include intermediary compounds or mixtures that are formed

during the manufacturing process.⁴ Plaintiffs explain that the specification of the '882 patent sets forth five examples. Plaintiffs concede that some of these disclosed embodiments (e.g., Example 2) illustrate final products that would indeed be suitable for administration to a patient. As Plaintiffs point out, however, other examples (e.g., Example 1) do not include ingredients that would be necessary for drug delivery (e.g., water and suspending agents), nor do they include other excipients such as sweeteners, colorants and/or flavorants as would be found in a form to be administered to patients. TR 22:18-24:14.⁵ Accordingly, Plaintiffs argue that a POSA reading the '882 patent would understand the term pharmaceutical composition to encompass compounds or mixtures formed in the preparation of a drug product (i.e., intermediary products) as well as those resulting from such preparation (i.e., final dosage forms).

⁴ Tris Pharma contends that Plaintiffs' suggestion that Example 1 is a preferred embodiment that is not a finished drug product is incorrect, as Example 1 is neither a preferred embodiment of the claimed invention nor referred to as a pharmaceutical composition in the specification. According to Tris Pharma, "Example 1 represents one step in arriving at the claimed 'pharmaceutical composition.' It is an intermediate only that is a raw material for Example 3, which further processes the result of Example 1 to produce a coated drug-resin complex. The coated drug-resin complex from Example 3, in turn, is then used to make a pharmaceutical composition in Example 4. It is the finished drug product of Example 4 that is a preferred embodiment of the claimed 'pharmaceutical composition,' as shown by the fact that it is the only material in the Example 1 - Example 2 - Example 3 sequence for which the results required by the claims are reported according to the claims' standard." Defendant's Responsive Brief, at *4-5. However, immediately preceding the examples, the specification states, "[t]he present invention is further illustrated by the following Examples which are not intended to be limiting." '882 patent, col. 13, ll. 38-39. Furthermore, none of the examples is referred to in the specification as "pharmaceutical compositions," including Example 4, the finished product. Lastly, Defendant's argument that Examples 1, 2, and 3 are not preferred embodiments simply because they are not final products is somewhat self-serving; indeed, one must necessarily adopt Defendant's proposed construction in order to arrive at that conclusion.

⁵ TR refers to the transcript of the Markman hearing the Court conducted on July 21, 2010.

In this Court's view, however, Plaintiffs' proposed construction is overbroad. By defining "pharmaceutical composition" as "a compound or mixture formed in or as a result of the preparation of a drug product," practically anything used in the formation of the final drug product would be considered a "pharmaceutical composition." For example, the specification states that "[m]ost resins [used to form a drug-resin complex] are sold in dehydrated form and then soaked in water prior to use." '882 patent, col. 2, ll. 4-5. Using Plaintiff's construction, just the act of soaking the resin in water in preparation for its use would be a "mixture formed in or as a result of the preparation of a drug product," even though at that point, the resin "mixture" can still be used for any purpose, including non-pharmaceutical usage; it may be intended to be used in the process of forming a pharmaceutical drug, but it has not yet acquired any property pharmaceutical in nature. In fact, Plaintiff's own expert witness, Dr. Steven Robert Byrn, admitted to the broad nature of this definition during the Markman hearing. TR 59:22-60:25. To define a technical term based on the intention of the party using it, and not by the actual physical properties of the substance involved, raises more uncertainty than it eliminates.

However, Defendant's proposed construction is equally problematic, as it unnecessarily narrows the claim scope and renders it inconsistent with the claim language. As used throughout the patent, nowhere is the term "pharmaceutical composition" used definitively as something that is "suitable for administration to a patient." In fact, Claim 27 specifically states "[a] method for administering a drug to a patient in need thereof, comprising . . . (a) providing a pharmaceutical composition that contains a drug-resin complex that contains the drug; (b) adding a chelating agent" '882 patent, col. 20, ll. 48-51 (emphasis added). In this context, the usage of the term "pharmaceutical

composition” is clearly intended to designate something other than “a drug product suitable for administration to a patient;” it merely refers to a component of the final product that is to be administered to a patient.

Thus the Court adopts neither of the parties’ proposed constructions, since “[t]he trial judge alone has the duty and responsibility to interpret the claims at issue.” Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1556 (Fed. Cir. 1995). “In any event, the judge’s task is not to decide which of the adversaries is correct. Instead the judge must independently assess the claims, the specification, and if necessary the prosecution history, and relevant extrinsic evidence, and declare the meaning of the claims.” Id. Here, the Court adopts the following construction for the term “pharmaceutical composition:” a compound or mixture containing the active ingredient of the final drug product.

The Court’s construction is consistent with the claim language. Every independent claim of the patent uses the term “pharmaceutical composition” as comprising at least a drug-resin complex. See ‘882 patent, Claims 1, 17-23, 27. Additionally, as Claim 27 above clearly denotes, that component drug-resin complex is intended to contain the active ingredient to be administered to the patient. Thus, every “pharmaceutical composition” contains at least the active ingredient. Furthermore, such a construction is consistent with the plain and ordinary meaning of the term. Merriam-Webster’s Medical Dictionary defines “pharmaceutical” as “a medicinal drug.” *Merriam-Webster’s Medical Dictionary*, Merriam-Webster, Inc. Therefore, a “pharmaceutical composition” should at least be construed under the ‘882 patent to contain the active ingredient that will produce the desired medicinal effect in the final drug product. This construction obviates the

overbreadth of Plaintiff's proposed construction, while avoiding the overly narrow construction proposed by Defendant that is inconsistent with the claim language.

Therefore the Court will construe the term "pharmaceutical composition" as "a compound or mixture containing the active ingredient of the final drug product."

B. A method for improving the stability of a pharmaceutical composition that contains a drug-resin complex comprising adding a chelating agent in an amount effective to reduce the rate of degradation of the drug in the drug resin complex by more than 20 percent over twelve months of storage at room temperature relative to an otherwise identical pharmaceutical composition without chelating agent (Claim 23)

Plaintiffs' Proposed Construction	Tris Pharma's Proposed Construction
A method for improving the stability of a <u>pharmaceutical composition</u> that contains a drug-resin complex by <u>including a chelating agent at any time during the manufacturing process</u> in an amount effective to reduce the rate of degradation of the drug in the drug-resin complex by more than 20 percent over twelve months of storage at room temperature relative to an otherwise identical pharmaceutical composition without the chelating agent. <u>Other steps may be performed, including the addition and/or removal of ingredients, either before or after the inclusion of the chelating agent.</u>	A method for improving the stability of a <u>drug product suitable for administration to a patient</u> that contains a drug-resin complex by <u>adding to the drug product that contains a drug-resin complex a chelating agent that is EDTA or salt of EDTA</u> in an amount effective to reduce the rate of degradation of the drug in the drug-resin complex by more than 20 percent over twelve months of storage at room temperature relative to an otherwise identical drug product without the chelating agent.

The dispute in claim 23 centers on the underlined issues above. Specifically, the proper construction of "pharmaceutical composition", "adding a chelating agent" and "comprising."

Plaintiffs maintain that the term pharmaceutical composition is already being independently construed by the Court (as discussed in Section A, *supra*) and therefore need not be construed twice. With respect to the construction of "adding a chelating

agent” as recited in claim 23, Plaintiffs maintain that it means “including a chelating agent at any time during the manufacturing process.” Citing Webster’s Dictionary, Plaintiffs maintain that a POSA reading claim 23 would understand the ordinary and customary meaning of the word “add” is “to include as a member of a group.” According to Plaintiffs, a POSA would understand that claim 23 does not specify to what the chelating agent is added or at what stage in the manufacturing process it is added. Rather, the claim merely states that the method includes the step of adding the chelating agent in a specified amount. For comparison, Plaintiffs point to other claims/limitations that recite a specific order for the claimed methods. For example, Plaintiffs cite independent claim 19 (which is not asserted), noting that it is also directed to a method for making a pharmaceutical composition, but unlike asserted claim 23, claim 19 includes language specifying the order in which the steps are performed (e.g., “(b) drying the result of step (a) to form a solid,” “(c) suspending the result of step (b) . . .”). Plaintiffs maintain that a POSA reviewing the ’882 specification would plainly understand the described invention as encompassing the addition of the chelating agent at any time during the manufacturing process, as it provides as follows:

The present invention provides a method of using chelating agents to stabilize drugs which have been taken up by resins and, in particular, ion exchange resins. The drugs are not in solution, but rather present in the form of a drug-resin complex . . . The chelating agent may be added during the formation of the complex after its formation, or at any time during the process.

Plaintiffs Opening Br. at 16 (quoting the ’882 patent, col. 3, ll. 57-67). Plaintiffs argue that Tris Pharma seeks to improperly limit the addition of the chelating agent to only after the drug and resin have been complexed together. Plaintiffs reiterate that Tris Pharma’s

construction lacks support in the claim language, which does not recite when, or to what, the chelating agent is added. Further, Plaintiffs argue that the various portions of the '882 patent specification cited by Tris Pharma and which describe a preferred embodiment of the invention, may not be relied upon to limit the claims. As Plaintiffs point out, Federal Circuit precedent makes clear that a preferred embodiment described in the patent specification should not be read as a limitation on the claims. See Plaintiffs' Opening Br. at 17 (citing Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048 (Fed.Cir. 1994) ("although the specifications may well indicate that certain embodiments are preferred, particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments."); see also Vanguard Prod. Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1371-72 (Fed.Cir. 2000) (rejecting attempt to limit claim to only process of manufacture disclosed in the patent); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1471 (Fed.Cir. 1998)).

Finally, Plaintiffs argue that Tris Pharma's proposed construction of the claim language in claim 23 ignores the key term "comprising" and its well accepted meaning. Plaintiffs contend that the term "comprising" defines the scope of a claim with respect to what unrecited additional components or steps, if any, may be included in an accused product or process while still meeting the requirements of the claim. For support, Plaintiffs cite to the Manual of Patent Examining Procedure, which includes the notation that "the transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps." M.P.E.P. (2008) 2111.03 (quoting Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ 2d 1631, 1634 (Fed. Cir. 2003)).

Tris Pharma contends that the purported invention set forth in the specification requires that the term “a method for improving the stability of a pharmaceutical composition that contains a drug-resin complex comprising adding a chelating agent in an amount effective to reduce the rate of degradation of the drug in the drug resin complex by more than 20 percent over twelve months of storage at room temperature relative to an otherwise identical pharmaceutical composition without chelating agent” be construed to require that the chelating agent be present in the finished pharmaceutical composition. Noting that Federal Circuit precedent requires claims terms to be construed to reflect the patentee’s purported invention set forth in the specification, see On Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d 1331, 1340 (Fed.Cir. 2006), Tris Pharma argues that here, where the purported invention is a dextromethorphan formulation containing EDTA to improve shelf-life of the product, it is clear that the patentee intended that the chelating agent remain in the finished drug product to prevent the degradation of the drug. Tris Pharma points to the specification, which states:

The invention provides a pharmaceutical composition comprising a drug-resin complex and a chelating agent in which the composition is in the form of a solid or a gel.

(’882 patent, col. 3, ll. 27-29; col. 3, ll. 37-41). Additionally, Tris Pharma contends that the importance of the chelating agent being present in the pharmaceutical composition in order to stabilize the drug in the drug-resin complex is also set forth in the specification, which further states:

Without the chelating agent, the complexed drug would be degraded by oxidation reactions or hydrolytic reactions catalyzed by metal ions.

('882 patent, col. 4, ll. 22-24). Accordingly, Tris Pharma asserts that the patentee intended the chelating agent remain in the finished drug product to prevent the degradation of the drug. Tris Pharma contends that the language in claim 23 that the chelating agent “reduce the amount of degradation of the drug in the drug-resin complex . . . relative to an otherwise identical pharmaceutical composition without chelating agent” also evidences that the purported invention requires the chelating agent be present in the finished product. Thus, Tris Pharma contends that the EDTA must be present in the finished drug product because otherwise the claimed result of improved stability set forth in claim 23 would not be achieved.

Further, Tris Pharma contends that, consistent with its interpretation that EDTA must be in the finished product, is the fact that the specification discloses specific amounts of EDTA that should be present in the final dosage:

The chelating agent can be present in a concentration of from 0.001 percent to 10 percent by weight, more preferably from 0.1 to 5 percent by weight. Most preferably, the concentration of the chelating agent is about 0.3 to 0.4 percent by weight for a solid dosage form. For dosage form which is a suspension, the concentration of chelating agent is most preferably about 0.05% by weight.

And:

The content of EDTA in the drug-resin complex in the final dosage form may vary from about 0.001% to 10% by weight, but is preferably about 0.1 to 0.75% by weight for solid dosage forms and 0.005% to 0.2% by weight for suspension.

('882 patent at col. 4, ll. 56-62; col. 12, ll. 54-59). Tris Pharma argues that the fact that there is no corresponding disclosure of the amount of chelating agent that should be present in any intermediate compositions means that the chelating agent must be present in the final drug product suitable for administration to a patient. Tris Pharma cites

multiple sections of the specification, which it argues, describe the chelating agent as being present in the final pharmaceutical composition.⁶

Tris Pharma also contends that the exemplary embodiments set forth in the '882 patent also disclose that EDTA is present in the finished drug product. Examples 1 and 3, Tris Pharma argues, set forth a method for making a finished drug product containing a drug-resin complex and a chelating agent (EDTA) and a similar finished drug product without the chelating agent. (See the '882 patent at col. 14, l. 43 - col. 15, l. 24).

⁶882, col. 6, ll. 14-31:

The chelating agent preferably is present in an amount effective to reduce the rate of degradation of the drug in the drug-resin complex by 20 percent over twelve months of storage at room temperature relative to an otherwise identical pharmaceutical composition without the chelating agent. In a preferred embodiment, the agent is present in an amount effective to reduce the rate of degradation of the drug in the drug-resin complex by 30 percent over twelve months of storage at room temperature, and in another preferred embodiment, the agent is present in an amount effective to reduce the rate of degradation of the drug in the drug-resin complex by 50 percent over twelve months of storage at room temperature.

'882 at Abstract; col. 3, ll. 27-29; col. 3, ll. 37-41:

The invention provides a pharmaceutical composition comprising a drug-resin complex and a chelating agent in which the composition is in the form of a solid or a gel. The invention also provides a method of making such a composition and a method for improving the stability of a pharmaceutical composition.

The invention provides a pharmaceutical composition comprising a drug-resin complex and a chelating agent, in which the composition is in the form of a solid or a gel.

The invention also provides a method for improving the stability of a pharmaceutical composition that contains a drug-resin complex comprising adding a chelating agent in an amount effective to reduce the rate of degradation of the drug in the drug-resin complex.

According to Tris Pharma, Example 2 also evidences the fact that EDTA is present in the finished drug product when it is added to the final suspension and dissolved, as it states:

A liquid suspension of dextromethorphan polystyrene was prepared in an aqueous vehicle. The aqueous vehicle contained sucrose, high fructose corn syrup, microcrystalline cellulose, carboxymethylcellulose, xanthan gum, orange flavors, methyl and propylparaben, and propylene glycol.

Disodium edetate (0.05% by weight) was added to the suspension and dissolved.

(The '882 patent, col. 14, ll. 3-10). Tris Pharma contends that Examples 4 and 5 also disclose a final drug product that contains EDTA, with the notation that in Example 5, while the chelating agent is present in the exemplary finished drug product, it is not present in the commercially available product. Example 4 provides, in relevant part, "The commercial PENTUSS suspension had the same composition as the experimental suspension except that there was no EDTA in the codeine polystyrene or in the suspension itself. (The 882 patent at col. 15, ll. 64-67).

Finally, Tris Pharma points to the prosecution history of the '882 patent, which it asserts confirms that the chelating agent is present in the final dosage form. Specifically, in the applicant's response to the initial rejection of its application as obvious, the applicant stated that the claimed pharmaceutical composition contained both a drug-resin complex and a chelating agent, which resulted in improved stability compared to pharmaceutical compositions that contain a drug-resin complex, but no chelating agent.

Upon close reading of the claim language, the Court agrees with Plaintiffs' construction. The Court is constrained to construe the scope of the claim first and foremost by the language of the claim itself. Old Town Canoe Co. v. Confluence Holdings Corp., 448 F.3d 1309, 1315 (Fed. Cir. 2006) ("We begin our claim construction

analysis with the words of the claim, which are generally given their ordinary and customary meaning”). “The claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 412 F.3d 1284, 1289 (Fed. Cir. 2005). In this case, the claim language itself does not specify when the chelating agent must be added, nor does it explicitly state that the chelating agent must be present in the final drug product. It merely states, “a method for improving the stability . . . comprising adding a chelating agent . . . to reduce the rate of degradation . . . relative to an otherwise identical pharmaceutical composition without chelating agent.” While Defendant is correct in noting that the specification is full of examples where the drug-resin is to be combined with the chelating agent within the final drug product, this alone cannot unnecessarily limit the claim scope, because no words or expressions of manifest exclusion or restriction were used when describing these examples.

Defendant’s best argument is that the final drug product would not attain decreased rate of degradation without the chelating agent present in the final product. Defendant’s expert witness, Dr. Harry George Brittain, testified that “[t]he act of taking [out the chelating agent] would leave the drug-resin complex unprotected, and an unprotected drug-resin complex then would be susceptible to whatever in the environment would then be capable of causing the oxidation. So it would not be a way to improve the stability. If anything, it would be a means towards enhancing instability.” TR 75:18-76:1. However, Defendant offers no evidence to substantiate its assertion other than bald conclusory statements, and repeated references to the examples given within the

specification; Dr Brittain called it “common sense” without any explanation, citation, or support. TR 121:11-25, 122:1-16.

However, as stated above, the examples themselves cannot serve to limit the claim scope as dictated by the claim language unless a manifest intent to expressly limit the scope of the claim is present, which in this case it is not. Furthermore, nothing in the intrinsic evidence explains or even suggests that the purpose of the patent would be frustrated if the chelating agent was removed from the final product. Without more, it is not “common sense,” at least not to this Court, why the absence of the chelating agent, after it has been used to remove the metal ions from the pharmaceutical composition, would somehow make the drug-resin complex even more unstable as Defendant claims; according to the patent, the removed ions are the cause of the degradation. The Court is not convinced that the final drug product must contain the chelating agent in order to effectively carry out the purpose of the patent, and in light of the fact that the claim language does not require the chelating agent to be present, the Court adopts Plaintiff’s proposed construction of Claim 23.

C. A method according to Claim 23 wherein the composition is a solid (Claim 24)

Plaintiffs’ Proposed Construction	Tris Pharma’s Proposed Construction
A method according to Claim 23 wherein the composition has a fixed shape <u>or is composed of particles, each having a fixed shape</u> .	A method according to Claim 23 wherein the composition has a fixed shape.

Claim 24 depends from claim 23 and adds the requirement that the finished drug product be a solid. The only point of disagreement is whether the term “solid” includes a collection of particles each having a fixed shape, for example, as found in a powder, or

whether the finished product itself must have a fixed shape as in a pill or tablet. Plaintiffs contend that based on the express teachings of the '882 patent, as well as the ordinary and customary meaning of the term, the term solid should be construed so as to encompass powders. Plaintiffs explain that a POSA would understand from the '882 patent specification that the claimed invention is specifically described as including powders:

The pharmaceutical composition can be in the form of a tablet, a capsule, a powder, a lotion, a cream, or a suppository.

Plaintiffs' Opening Br. at 20 (quoting the '882 patent, col. 5, ll. 33-35).

Possible dosage forms include tablets, capsules, powders, syrups, suspensions, lotions, creams, suppositories, nasal sprays, inhalers, and eye drops, with suspensions being the preferred mode of administration.

Plaintiffs' Opening Br. at 20 (quoting the '882 patent, co. 5, ll. 33-35).

Tris Pharma contends that construction of the term "solid" in the context of claim 24 as having a fixed shape is consistent with the ordinary meaning of the term as understood by a POSA. According to Tris Pharma, this construction is confirmed by pharmaceutical references, which classify capsule and tablet dosage forms as solid dosage forms, but do not classify powders as solid dosage forms. Tris Pharma Opening Br. at 22. Tris Pharma argues that the term solid should not be construed to include particles each having a fixed shape because such construction is inconsistent with the usage of the term in the specification, which states: "The invention provides a pharmaceutical composition . . . in which the composition is in the form of a solid or a gel." (882 patent, col. 3, ll 27-29). Tris Pharma reasons that this language dictates that solid and gel are two distinct substances and that Plaintiffs' proposed construction would allow the term solid to

encompass gels and suspensions by including “or is composed of particles, each having a fixed shape.” Tris Pharma contends that Plaintiffs’ construction is overly broad and fails to ascribe a precise meaning to a claim term.

Based on the specification, the Court adopts Plaintiff’s construction. As stated above, it is clear that the specification intended a pharmaceutical composition that could be in either tablet, powder, or capsule form. Defendant’s use of pharmaceutical references is misleading, as those references refer to solid dosage forms. Claim 24 does not claim that the pharmaceutical composition referenced in Claim 23 has to be in solid dosage form; it merely has to be a solid.⁷ Dr. Brittain, Defendant’s expert, himself acknowledged that the word “solid” may be interpreted in a more classical, elementary way that merely differentiates it from being a liquid or gas. TR 95:19-96:17. The Court will not limit the claim scope beyond what is stated in the claim language, and therefore adopts Plaintiff’s proposed construction for Claim 24.

D. A method according to Claim 23 wherein the composition is a gel (Claim 25)

Plaintiffs’ Proposed Construction	Tris Pharma’s Proposed Construction
A according to Claim 23 wherein the composition is a semi-solid.	A method according to Claim 23 wherein the composition is <u>non-pourable</u> , semi-solid

The dispute with respect to claim 25 centers on whether “gel” is required to be non-pourable. Tris Pharma contends that gel in the context of claim 25 means a non-

⁷ The American Heritage Science Dictionary defines solid as “one of four main states of matter, in which the molecules vibrate about fixed positions and cannot migrate to other positions in the substance.” *The American Heritage® Science Dictionary*, Houghton Mifflin Company (emphasis added). Clearly, a substance in powder form is still considered a solid.

pourable, semi-solid composition, which construction is consistent with the ordinary meaning of the term as understood by a POSA. Tris Pharma argues that its interpretation is confirmed by pharmaceutical references which consistently define gel as a non-pourable, semi-solid.

Plaintiffs contend that the ordinary and customary meaning of the term gel, as well as the lack of any intrinsic evidence supportive of Tris Pharma's interpretation, mandate a finding that the correct construction of the term gel cannot include the additional requirement that gel be non-pourable. Plaintiffs points out that Tris Pharma's expert agreed that semi-solids have the ability to flow, and conceded that there was nothing in the intrinsic evidence which expressly requires that a gel be non-pourable. Further Plaintiffs note that only one of the nine extrinsic references cited by Tris Pharma refers to gels as being "not pourable" at room temperature. That reference, the 2006 "FDA Drug Nomenclature Monograph – Dosage Form," lists various drug dosage forms, and defines a "gel" as being a "semisolid dosage form." Then, in a footnote, the term "semisolid" is described as being "not pourable" at room temperature. Plaintiffs contend that Tris Pharma's reliance on this 2006 reference, published nearly a decade after the 1997 filing of the '882 patent, is improper as claim terms are defined as of the date of the filing of the patent. Plaintiffs Responsive Br. at 24 (citing Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005)). Even if reliance on the 2006 reference were proper, Plaintiffs argue that it is telling that Tris Pharma can only cite to one reference in support of its theory – and then only to a footnote in that reference.

A review of the specification reveals no insight into whether the word "gel," as used in the patent, requires said substance to be "non-pourable." Therefore, in order for

Defendant's proposed construction to prevail, the word "gel" itself would have to, by definition, be non-pourable. Both Plaintiff and Defendant cite to various extrinsic references to attempt to define the word "gel," but the only conclusion the Court can draw from these various sources on whether a "gel" may be pourable is: it depends. Defendant provides no explanation why it would be important to construe the term "gel" more narrowly, or how it would be more consistent with the purpose and function of the patent itself if it were to be construed more narrowly. The American Heritage Stedman's Medical Dictionary defines "gel" as "a colloid in which the disperse phase combined with the dispersion medium to produce a semisolid material." *The American Heritage® Stedman's Medical Dictionary*, Houghton Mifflin Company. There is no mention that a gel is "non-pourable." Thus, the Court finds no reason to impose an artificial limitation on a claim term that neither party has conclusively proved or disproved, and therefore adopts Plaintiff's simpler, albeit broader, proposed construction.

E. The Unasserted Claims (Claims 5, 6, 14 and 15)

Unasserted Claim Language	Tris Pharma's Proposed Construction
A pharmaceutical composition wherein the chelating agent is not covalently bound to the drug resin complex (unasserted Claim 5)	<u>a drug product suitable for administration to a patient</u> wherein the chelating agent, present in the recited amount, is not covalently bound to the drug resin-complex in the drug product.
A pharmaceutical composition wherein the chelating agent is covalently bound to the drug resin complex (unasserted Claim 6)	<u>a drug product suitable for administration to a patient</u> wherein the chelating agent, present in the recited amount, is covalently bound to the drug resin-complex in the drug product.
The pharmaceutical composition is suitable for oral, topical, rectal, vaginal, nasal, or ophthalmic administration (unasserted Claim 14)	<u>the drug product</u> is properly administered by mouth, to the skin, in the rectum, in the vagina, in the nose, or in the eye
the pharmaceutical composition is in the form of a tablet, a capsule, a powder, a lotion, a cream, or a suppository (unasserted Claim 15)	<u>the drug product</u> is a tablet, capsule, powder, lotion, cream, or suppository

Tris Pharma contends that construction of unasserted claims 5, 6, 14 and 15 is necessary to determine whether the claims of the '882 patent are enabled by the specification and have written description support under 35 U.S.C. § 112.

Tris Pharma explains that claims 5 and 6 recite that the pharmaceutical composition contains a chelating agent that either is or is not covalently bound to the drug-resin complex. Tris Pharma contends that the specification does not enable a POSA to make and use a pharmaceutical composition in which the chelating agent is covalently bound to the drug-resin complex. Accordingly, Tris Pharma argues that construction of claims 5 and 6 is necessary to determine what is meant by the chelating agent and drug resin complex being covalently bound in the pharmaceutical composition in order to

adjudicate Tris Pharma's § 112 invalidity defenses. Tris Pharma suggests that Plaintiffs are attempting to escape Tris Pharma's invalidity defenses by avoiding construction of the pertinent terms. Because Plaintiffs have refused to submit a construction, Tris Pharma argues that its construction should be accepted as unopposed.

With regard to the construction of claims 14 and 15, Tris Pharma contends that they provide that the same pharmaceutical composition of claim 23 be administered using certain routes of administration and using certain dosages, yet there is no enabling disclosure as to how to make a pharmaceutical composition into one of the specified dosage forms or how to administer the pharmaceutical composition to a patient using one of the specified routes of administration. Accordingly, Tris Pharma contends that construction of claims 14 and 15 is necessary to determine the meaning and scope of pharmaceutical composition in order to evaluate the written description and enablement issues.

Plaintiffs urge this Court to deny Tris Pharma's request that claims 5, 6, 14 and 15 be construed as they are not asserted, do not depend on asserted claims, and do nothing but reiterate claim construction issues already separately before the Court. Plaintiffs contend that, contrary to Tris Pharma's suggestion, these dependent claims do not give meaning to the term "pharmaceutical composition" in claim 23. For example, Plaintiffs point out that while Tris Pharma asserts that composition claims 5 and 6 support its construction because these claims are directed to the bonds between the drug-resin complex and chelating agent, and, therefore, the chelating agent must be present in the pharmaceutical composition, such analysis is inapplicable to claim 23, which is a process of making a pharmaceutical composition. Plaintiffs reason that whether these unasserted

claims contemplate the presence of the chelating agent at the same time as the drug-resin complex is of no consequence to claim 23 because claim 23 is not so restricted. Plaintiffs point out that claims 5, 6, 14 and 15 depend from composition claim 1 – not process claim 23 – and argue that importing limitations from dependent claims into an independent claim from which they do not depend is plainly contrary to the principles of claim construction.

Further, Plaintiffs contend that Tris Pharma's argument that the specification does not enable a POSA to make and use a pharmaceutical composition in which the chelating agent is covalently bound to the drug-resin complex, as required in claim 6, and its argument that the construction of claims 14 and 15, claiming particular dosage forms and routes of administration is necessary because these claims are likewise not enabled, are in essence invalidity arguments improperly raised under the guise of claim construction. Plaintiffs point out that whether a claim recites subject matter that is sufficiently definite is an invalidity challenge under 35 U.S.C. § 112, and that resolution of invalidity will require findings of fact on issues that have not been fully presented and have no place in the claim construction process. See Plaintiffs' Responsive Br. at 25 (citing Phillips, 415, F.3d at 1328 (invalidity considerations have 'no applicability' to claim construction); Rhine v. Casio, Inc., 183 F.3d 1342, 1346 (Fed. Cir. 1999); MacNeill Eng'g Co., Inc. v. Trisport, Ltd., 126 F.Supp.2d 51, 54 n.1 (D.Mass. 2001) ("[W]hen Markman hearings become miniature or full blown infringement trials, the actual language of the claim diminishes in importance relative to the context of the particular dispute, despite the Supreme Court's admonition that it was the judiciary's particular facility for construing

language that warranted denoting claim construction as a legal . . . function”)). The Court agrees.

Defendant argues that Claims 5, 6, 14 and 15 must be construed to give effect to Defendant’s invalidity defense; this is certainly true, as any invalidity defense would require a properly construed claim in order to clearly define the scope of the claim before a determination of validity can be made. However, Defendant does not explain how or why the term “pharmaceutical composition” needs to be construed differently in Claims 5, 6, 14 and 15 from its usage throughout the rest of the patent; in fact, the Court finds that these claims, as dependent claims to Claim 1, must be construed consistently with the rest of the claims. As Defendant does not raise any claim construction issues with regard to Claims 5, 6, 14 and 15, other than the term “pharmaceutical composition,” and Plaintiffs have already responded and submitted their proposed construction of the term “pharmaceutical composition,” the Court finds Plaintiff’s failure to respond specifically to the construction of the unasserted Claims 5, 6, 14 and 15 irrelevant to the purpose of this Opinion, and the Court will construe these claims consistent with its findings within this Opinion.

IV. CONCLUSION

For the foregoing reasons, the following chart summarizes the Court's constructions of the disputed claim terms:

Disputed Terms	Plaintiffs' Proposed Construction	Defendant's Proposed Construction	Court's Determinations
Pharmaceutical Composition	A compound or mixture formed in or as a result of the preparation of a drug product	A drug product suitable for administration to a patient	A compound or mixture containing a drug-resin complex that forms the active ingredient of the final drug product
comprising adding a chelating agent	by including a chelating agent at any time during the manufacturing process	by adding to the drug product that contains a drug-resin complex a chelating agent that is EDTA or salt of EDTA	by including a chelating agent at any time during the manufacturing process
solid	has a fixed shape or is composed of particles, each having a fixed shape	has a fixed shape	has a fixed shape or is composed of particles, each having a fixed shape
gel	semi-solid	non-pourable, semi-solid	semi-solid

/s/ Freda L. Wolfson
Honorable Freda L. Wolfson
United States District Judge

Dated: November 16, 2010